

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
Christopher D. ENDARA et al.	)	Group Art Unit: 3734
U.S. Patent No.: 7,534,253 B2	)	Examiner: Kevin Thao Truong
Issue Date: May 19, 2009	)	
Application No.: 10/731,153	)	Confirmation No.: 4806
Filed: December 10, 2003	)	
For: CLEVIS ASSEMBLIES FOR	)	
MEDICAL INSTRUMENTS AND	)	
METHODS OF MANUFACTURE OF	)	
SAME	)	

**BOX: PETITIONS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PETITION UNDER 37 C.F.R. § 1.181 REQUESTING REVIEW OF THE  
DISMISSAL OF PATENTEE'S REQUEST FOR RECONSIDERATION OF PATENT  
TERM ADJUSTMENT**

Patentee petitions the Director under the provisions of 37 C.F.R. § 1.181 for review and reconsideration of the Decision on Request for Reconsideration of Patent Term Adjustment mailed by the Office of Petitions on September 16, 2009 ("the Decision").

The United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,534,253 B2 ("the '253 patent") on May 19, 2009, with a patent term adjustment of 758

days. On June 22, 2009, Patentee filed a Request for Reconsideration of Patent Term Adjustment under 37 C.F.R. § 1.705(d) requesting an additional 254 days of patent term adjustment pursuant to the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008).

Patentee calculated the additional 254 days of patent term adjustment based on the following facts:

The application for this patent was filed on December 10, 2003. The first non-final Office Action on the merits was mailed on April 3, 2007, creating a U.S. Patent and Trademark Office (PTO) delay of 782 days beyond the 14 months provided by 35 U.S.C. § 154(b)(1)(A)(i). A response to the April 3, 2007 Office Action was filed July 3, 2007, resulting in no reduction in patent term adjustment. A final Office Action was mailed on August 20, 2007, resulting in no increase in patent term adjustment. An Amendment and Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 was filed on December 13, 2007 in response to the August 20, 2007 final Office Action, resulting in a delay by Applicants of 21 days beyond the 3 months provided by 35 U.S.C. § 154(b)(2)(c)(ii).

A second non-final Office Action was mailed on January 10, 2008, resulting in no increase in patent term adjustment. A response to the January 10, 2008 Office Action was filed on April 14, 2008, resulting in an additional delay by Applicants of 4 days beyond the 3 months provided by 35 U.S.C. § 154(b)(2)(c)(ii). A second final Office Action was mailed on July 14, 2008, resulting in no increase in patent term adjustment. A response to the July 14, 2008 final Office Action was filed on September 11, 2008, resulting in no reduction in patent term adjustment. A Notice of Allowance was mailed

January 12, 2009, resulting in a PTO delay of 1 day beyond the 4 months provided by 35 U.S.C. § 154(b)(1)(A)(ii).

The issue fee was paid on April 9, 2009, and the '253 patent issued on May 19, 2009.

Under *Wyeth v. Dudas*, the period of patent term extension under 35 U.S.C. § 154(b)(1)(B) begins to toll three years after the filing date of the application, i.e., three years from December 10, 2003. Thus, the period of patent term extension under 35 U.S.C. § 154(b)(1)(B) began to toll on December 10, 2006, and ended with the filing of a Request for Continued Examination (RCE) on December 13, 2007, resulting in 368 days of PTO delay under the three-year pendency rule. Of which, 114 days exceeding the three-year pendency date overlap with the earlier 782 days of PTO delay. Accordingly, the PTO delay under the three-year pendency rule is 254 days ( $368 - 114 = 254$  days).

*Wyeth v. Dudas* instructs that the 254 days of PTO delay under the three-year pendency rule provided by 35 U.S.C. § 154(b)(1)(B) should be counted in addition to the PTO examination delay of 783 days under the 14 month delay provided by 35 U.S.C. § 154(b)(1)(A)(i) and 4 month delay provided by 35 U.S.C. § 154(b)(1)(A)(ii) offset by 25 days of Applicants' delay. Thus, the total of PTO patent term adjustment for the '253 patent based on delay is 1012 days.

On September 16, 2009, the PTO denied Patentee's request for additional patent term beyond the original 758 days. The PTO's basis for denying Patentee's request was that the Patentee's calculation of the period of overlap was inconsistent with the PTO's interpretation of 35 U.S.C. 154(b)(2)(A) and 37 C.F.R. § 1.703(f). More

particularly, the PTO asserted that the entire period of PTO examination delay, and not only the period of PTO examination delay that occurred after the date that was three years after the actual filing date of the '253 application, was the period of overlap between the delay provided by 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) under 35 U.S.C. § 154(b)(2)(A). Respectfully, such a position ignores the district court's decision in *Wyeth v. Dudas*.

Under 35 U.S.C. § 2(b)(2)(a), the PTO has a duty to establish regulations "not inconsistent with the law." In *Wyeth v. Dudas*, the district court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. In accordance with *Wyeth v. Dudas*, the patent term adjustment for the '253 patent is 1012 days, as set forth above and in Patentee's Request for Reconsideration of Patent Term Adjustment filed June 22, 2009. The PTO's refusal to implement the district court's decision regarding the proper statutory interpretation, or to at least hold requests for correction in abeyance while the *Wyeth* appeal is pending, is inconsistent with the current law and contrary to its duty to patentees eligible for patent term adjustment. Accordingly, Patentee requests that the Director review the dismissal of Patentee's Request for Reconsideration of Patent Term Adjustment.

Indeed, Patentee requests that the Director await the outcome of the *Wyeth* appeal before taking any action on Patentee's petition under 37 C.F.R. § 1.181 to review the dismissal of Patentee's Request for Reconsideration of Patent Term Adjustment. Upon resolution of the appeal, Patentee requests that the Director exercise his supervisory authority to review and reconsider Patentee's Request for

Reconsideration of Patent Term Adjustment and issue a decision on the petition that is consistent with the final outcome of the *Wyeth* appeal.

If there are any fees due in connection with the filing of this request, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: November 16, 2009

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